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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,071	12/18/2001	Kurt R. Linberg	P-8558.04	3669

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,071	LINBERG, KURT R.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-29 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-29 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 12, 2004 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 16-29 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al. (Pat. No. 5,300,120) in view of Strandberg (Pat. No. 4,886,064). Concerning claim 16, Knapp et al. disclose at least one medical component (note col. 5, lines 3-12), a programmer 34/36 capable of identifying the medical component implanted, a remote expert data center positioned globally at a distal location relative to the programmer (see col. 2, lines 29-37 and col. 4, lines 1-7), an interface between the programmer and the remote expert data center (e.g., the telephone and modem discussed in columns 2 and 4), and an inventory control module 38 (or equivalent data bank control computer/module at the remote site) in data communication with the remote expert data center for receiving information identifying the medical component implanted in the patient and for updating an inventory module (data bank) regarding inventory of the medical component implanted in the patient as required by the Safe Medical Device Act of 1990 (note col. 1, lines 14-37 and claim 1).

Although Knapp et al. doesn't explicitly refer to an implanted medical device system (the examiner considers a collection of implanted components to collectively constitute an implanted medical device system) comprising a plurality of medical components operatively coupled together, as it is well-established that a single patient may need more than one component simply depending on his/her condition, those artisans of ordinary skill in the art would have seen the provision of a system of components as obvious. In the case of breast implants (note col. 1, line 12), two implants would normally be required –each with a transponder. The examiner further considers the programmer of Knapp et al. capable of identifying each medical component by virtue of the fact that each transponder may be encoded with one of about a trillion different code combinations (col. 3, lines 42-44) to allow for a unique identification tag signal (note claim 1), and thus allow for an update of the inventory of each component.

Regarding the phrase "operatively coupled together," Strandberg discloses a plurality of medical components operatively coupled together to form a system (see Fig. 2). Clearly the teachings of Knapp et al. were never intended to be limited to a specific type of system, and apply to a wide variety of devices --including pacemakers-- as disclosed in col. 1, lines 7-14. Any artisan desiring to abide by the *Safe Medical Device Act of 1990* and keep inventory of the pacemaker and individual sensors disclosed by Strandberg would have seen the obvious of utilizing the invention of Knapp et al. to do so.

Regarding the use of a programmer, the examiner considers the decoder/controller 36 to constitute such structure in the absence of any means-plus-function language. In any event, the examiner took Official Notice in the prior Office Action that the use of programmers in conjunction with pacemakers, defibrillators, or other controllable medical devices as a means to receive transmitted data is old and well-known. To therefore utilize a programmer already known and specifically designed to receive transmitted information for receiving the transponder signal discussed by Knapp et al., would have been considered obvious by those of ordinary skill in the implantable medical device field.

Regarding claims 17 and 18, note col. 1, line 12.

Regarding the use of a defibrillator (claim 19), Knapp et al. disclose that a wide variety of implants may be employed in the invention, with the scope of the invention being broad enough to encompass any implant presently known to the inventors (col. 5, lines 3-12). It is axiomatic that implantable defibrillators are widely known to artisans of ordinary skill in the medical field. To employ an implantable defibrillator would have therefore been considered blatantly obvious.

Likewise for claim 20, since leads are known implants in medical systems and in wide use, those of ordinary skill in the art would have seen the obviousness of utilizing the system of Knapp et al. to identify any implanted leads.

Regarding claims 21, 22, 24-26, note col. 2, lines 29-32. Clearly any suitable form of communication link in known use and associated with data transfer such as LAN, the Internet, satellite communications, GPS, etc., would have been considered a matter of obvious design by the network engineer. These systems are well-known in conjunction with computerized data transfer, with the number of links and the type of links employed being a matter of obvious design and dictated by the communication systems available for the particular location involved. A combination of links may be required, for example, to access the centralized site in remote areas absent reliable telephone communication lines.

Regarding claim 27, those of ordinary skill in the art would have seen the particular coding method employed to identify the component as an obvious matter of design based upon what technique was found to be most suitable for the situation at hand and the available decoder equipment in use.

Concerning claims 28 and 29, although Knapp et al. do not explicitly discuss identifying the serial number and/or model number, the Safe Device Medical Act of 1990 discussed in col. 1 of the Knapp et al. reference does require such information. To design the system to abide by this Act would have therefore been considered obvious by any ethical medical device artisan.

4. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al. (Pat. No. 5,300,120).

Concerning claim 59, comments paralleling those made above in the rejection of claim 16 as it relates to the Knapp et al. reference apply here as well.

Considering the fact that there must be some means available to enter device/patient specific information into the remote data bank, and given the fact that Knapp et al. discourage the use of a return card or form that could get lost or misdirected (col. 1, lines 21-32), it would have been obvious to one of ordinary skill in the art that one could employ telecommunications via the programmer/controller or local computer to transmit such inventory information at the site for storage at a central locale for later read-back.

Response to Arguments

5. Applicant's arguments filed October 12, 2004 have been fully considered but they are not persuasive.

6. The applicant previously argued that the device of Knapp simply emits a code that can be used by a data bank to access stored information. It was further argued that the data bank of Knapp is nothing more than...

> *A collection of information relating to the implanted component fitted with the particular transponder, which information can be accessed for review by the controller. There is no suggestion whatsoever that the data bank provides or can provide any inventory control function. Further, there is absolutely no basis whatsoever to support the characterization of the data bank in Knapp as involving inventory control of the implanted components fitted with the transponder.*

Assuming *arguendo* that the device of Knapp merely emits a code that the central data bank uses to access information germane to the particular implant, it still does not negate the fact that the remote expert data center must have a module for receiving this identifying information (e.g., a computer or control module). The module or computer must also be capable of updating an inventory module (e.g., memory bank) if it is to enable one to store such current information as patient demographics, surgeon's name, date of implant, etc.. The data in the memory bank must be entered in some manner, whether it be automatically via the programmer or manually via a

registration card system (see col. 1, lines 21-37). It would be counter-intuitive to develop a data bank that could not be updated as devices are implanted.

Regarding the assertion that the data bank does not provide any inventory control function, the broadest reasonable interpretation of the word "inventory" would include a mere listing of information such as described in col. 2, lines 35-37. As stated in the Knapp disclosure, the *Safe Medical Device Act of 1990* dictates that a device registry be implemented to track devices, notify patients and monitor implants after they have been implanted. If the data contained within the central data bank cannot provide any inventory control function as asserted by the applicant, then it is unclear what its purpose is. Any device that allows one to track and monitor implants will be considered by the examiner to constitute an inventory control function.

The applicant currently argues that the prior Office Action "...merely offers, without support, that 'the broadest reasonable interpretation of the word *inventory* would include a mere listing of information such as described in col. 2, lines 35-37." As stated in the Advisory Action mailed September 2, 2004, support for this definition can be found in Webster's New World Dictionary, 3rd College edition. The word *inventory* as defined by Webster's pertains to "any detailed list...or the act of making such a list." The broadest reasonable interpretation of the word *inventory* would therefore include a listing of information as described above, despite the claim by applicant that it only applies to "...the quantity of goods or materials on hand: stock."

The examiner further wishes to point out that the applicant's apparatus claims -- and specifically the inventory control module recitation-- do not come under the purview of §112, sixth paragraph. Application of the prior art is therefore not limited to the specific structure or materials disclosed in the specification and equivalents thereof.

Even if the claim language was to be limited as such, Knapp explicitly teaches the need to track medical implant devices and provides a solution to the problems of careful data accumulation and securing inventory control (note col. 1, lines 7-37).

In response to the applicant's assertion that the data contained within the central data bank has no inventory control function associated with it or purpose other than to comply with the Safe Medical Device Act of 1990, the obvious question then becomes,

"What is the purpose of the Safe Medical Device Act of 1990?" Knapp clearly states in col. 1 that the purpose of the Act is to "...institute a device registry for *tracking* [emphasis added] of their devices, notification of patients, and otherwise monitoring these implants after they have been placed in a patient." It is further stated that tracking requires "...careful accumulation of data by a surgeon or his staff as well as secure *inventory control* [emphasis added]... ."

In summary, the word *inventory* may be reasonably and broadly defined as a list of information, the applicant's claims do not come under the purview of §112, 6th paragraph, and the Safe Medical Device Act of 1990 requires implant tracking and inventory control. Any artisan of ordinary skill in the art would have therefore seen the obviousness and necessity of utilizing an inventory control module in the device of Knapp.

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
December 20, 2004

KENNEDY SCHAETZLE
PRIMARY EXAMINER